

## REMARKS

Claims 1-165 are pending the application. Claims 152-165 have been newly added. Support for newly added claim 152 can be found on page 25, lines 22-31 and on page 27, line 30 to page 28, line 34, for example. Support for claims 153-159 is found in original claims 135-140. Support for claims 160-164 can be found in original claims 129 and 142-145, respectively. Support for claim 165 can be found in original claim 137 and on page 28, lines 13-34. Applicants submit that no new matter has been added to the claims.

The Examiner has restricted the prosecution of the application to one of the following groups of claims:

Group I        Claims 1-39, drawn to a method of detecting inflammation in a subject.

Group II       Claims 40-67, drawn to a method of detecting inflammation in a transplant, post transplantation.

Group III      Claims 68-91, drawn to a method of monitoring inflammation in a subject with inflammatory or autoimmune disease.

Group IV      Claims 92-105, drawn to a method of identifying a vector capable of detecting inflammation.

Group V       Claims 106-123, drawn to a method of treating inflammatory disease, comprising detection of an expressed nucleic acid and modifying treatment upon detection.

Group VI      Claims 124-127, 130-132, and 134, drawn to treating inflammation in a subject by administration of a complement modulator.

Group VII     Claim 128, drawn to a transgenic animal.

Group VIII    Claim 129, drawn to a cell line comprising a vector with a reporter nucleic which is expressed under conditions of inflammation.

Group IX      Claims 133, 135, 136, 142-145, 150 and 151, drawn to a nucleic acid encoding at least two repeats of ED1 and a linker.

Group X       Claims 137-141, 146, and 147-149, drawn to a nucleic acid encoding

SEQ ID NO:8 with at least 80% identity.

Applicant hereby provisionally elects Group VI, as set forth in claims 124-127, 130-132, 134, and newly added claims 152-165, with traverse. Regarding the election of species, the Restriction Requirement requires that one species be elected from among SCR 13-15, Crry, (as in claims 126-127) and a specific complement inhibitor specifically supported by the specification. Applicants hereby elect a complement inhibitor specifically supported by the specification. This is SEQ ID NO: 9, as found in newly added claim 165. As mentioned above, support for this claim can be found on page 28, lines 13-34, for example.

Applicant respectfully requests that the restriction requirement and the election of species be reconsidered and withdrawn for at least two reasons:

- **The Restriction Requirement does not comply with M.P.E.P § 803**

Without conceding that the claims in the various Groups are not patentably distinct, Applicant respectfully asserts that the Action has not shown that a serious burden would be required to examine all of the pending claims of Groups VI and IX and X in the this application. Specifically, M.P.E.P § 803 provides:

If the search and examination of an application can be made without serious burden, the Examiner *must* examine it on the merits, even though it includes claims to distinct or independent inventions.  
(*Emphasis supplied.*)

Thus, for a restriction to be proper, the Office Action must satisfy the following two criteria: (1) the existence of independent and distinct inventions (35 U.S.C. § 121); and (2) that the search and examination of the entire application cannot be made without serious burden. See M.P.E.P § 803.

The Office Action has not shown that the second requirement has been met. Specifically, the Office Action has not shown that it would be a serious burden to search and examine all of the groups together. Indeed, the Office Action has not even alleged that it would be a serious

burden to search and examine all of the groups together. Consequently, reconsideration and modification or withdrawal of the restriction is requested.

- **The Action does not meet its burden for establishing lack of unity of invention**

Without conceding that the claims in the various Groups are not patentably distinct, Applicant respectfully asserts that the Restriction Requirement does not meet the requisite burden for establishing a lack of unity of invention. Specifically, 37 C.F.R. § 1.475 provides that national stage applications shall relate to one invention or to a group of inventions so linked as to form a single general inventive concept. Such inventions possess unity of invention. PCT Rule 13.2 states that

[T]he requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression “special technical features” shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

Thus, the requirement of a single inventive concept is fulfilled when there is a technical relationship within the claimed subject matter involving one or more of the same or corresponding special technical features, which define a contribution that the claimed subject matter makes over the prior art. Additionally, MPEP 1850 states that contributions over the prior art “should be considered with respect to novelty and inventive step.”

Applicant also respectfully requests that the requirement for species election be reconsidered, as the Examiner has not shown that a serious burden would result if all the species are examined together. M.P.E.P. § 803 provides that “[i]f the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or independent inventions.” (*Emphasis added.*) Thus, for a restriction requirement to be proper, the Examiner must satisfy the following two criteria: (1) the existence of independent and distinct inventions (35 U.S.C. § 121) and (2) the search and examination of the entire application cannot be made without serious burden. *See*

M.P.E.P. § 803. Applicant notes that the restriction requirement does not provide sufficient basis to indicate that examination of more than one of the “species” would overly burden the Examiner. Applicant thus respectfully requests reconsideration of the election requirement. Applicant reminds the Examiner that if the elected genus is found to be allowable, all of the species listed in claims 126-127 should also be found allowable.

Favorable consideration of claims 1-164 is earnestly solicited.

Pursuant to the above amendments and remarks, reconsideration and allowance of the pending application is believed to be warranted. The Examiner is invited and encouraged to directly contact the undersigned if such contact may enhance the efficient prosecution of this application to issue.

A credit card payment is being submitted via EFS Web in the amount of \$865.00, representing the fee for a small entity under 37 C.F.R. § 1.17(a)(4), together with a Request for Extension of Time. This amount is believed to be correct; however, the Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,

/Janell T. Cleveland/

\_\_\_\_\_  
Janell T. Cleveland  
Registration No. 53,848

BALLARD SPAHR ANDREWS &  
INGERSOLL, LLP  
Customer Number 23859  
(678) 420-9300  
(678) 420-9301 (fax)

CERTIFICATE OF ELECTRONIC TRANSMISSION UNDER 37 C.F.R. § 1.8			
I hereby certify that this correspondence, including any items indicated as attached or included, is being transmitted via electronic transmission via EFS-Web on the date indicated below.			
Name of Person Mailing (Print/Type)	Janell T. Cleveland		
Signature	/Janell T. Cleveland/	Date	November 20, 2008